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4 graft associated with self expanding spring apparatus
5 having a compressed state, said arrangement comprising an
6 outer sheath having a longitudinal bore for surrounding the
7 said assembly when the latter is at the said particular
8 position, said introducer sheath containing said self
9 expanding spring apparatus in said compressed state when
10 said spring apparatus is positioned in said longitudinal
11 bore of said introducer sheath, means for restraining axial
12 movement of the prosthesis assembly during at least partial
13 removal of the outer sheath, and means for disabling the
14 restraining means after the outer sheath has been withdrawn
15 from the self expanding spring apparatus and released said
16 self expanding spring apparatus from said compressed state
17 and the prosthesis assembly has self expanded to the said
18 internal wall.

Remarks

In the final Office action of July 1, 1993, Paper No. 14, claims 1, 2, 5, 9-11, 16, 17, 20, and 24-40 are pending and were rejected. Claims 3, 4, 6-8, 12-15, 18, 19, and 21-23 were previously canceled. In particular, claims 24 and 27 were rejected under 35 U.S.C. § 102(b) as being anticipated by the Choudhury reference. Claims 1, 2, 5, 9-11, 16, 17, 20, 25, 26, and 28-40 were rejected under 35 U.S.C. § 103 as being unpatentable over the Choudhury reference in view of the Kremer reference.

By this amendment, independent claims 1, 20, 24, 28, 29, 31, 39, and 40 and dependent claim 27 are being amended to more particularly point out and distinctly claim the subject matter sought to be patented and to further distinguish the claims over the cited references. In particular, the subject matter of dependent claim 25 is being included in independent claim 24, as amended herein. Accordingly, dependent claim 25 is being canceled.

Applicant's invention as claimed in independent claim 24, as amended herein, is directed to a transluminal arrangement for positioning a prosthesis assembly at a particular position on the

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wall of a vessel lumen. The transluminal arrangement comprises an introducer sheath having a longitudinal bore therein. The arrangement also comprises a prosthesis assembly including a graft having a longitudinal bore and a self expanding spring assembly having a compressed state. The introducer sheath contains the self expanding spring assembly in the compressed state when the self expanding spring assembly is positioned in the longitudinal bore of the introducer sheath. The self expanding spring assembly expands the graft to substantially conform the graft at a particular position on an interior wall of a lumen after the prosthesis assembly has been positioned in the lumen and the self expanding spring assembly has been released from its compressed state. The transluminal arrangement also comprises means positioned in the bore of the graft for retaining the prosthesis assembly at the particular position in the lumen when withdrawing the introducer sheath from the self expanding spring assembly and releasing the self expanding spring assembly from its compressed state. In dependent claim 27, the transluminal arrangement further comprises means for releasing the prosthesis assembly from the retaining means after the introducer sheath has been withdrawn from the prosthesis assembly.

As previously discussed in the response to the first Office action, the Choudhury patent is directed to a method and article for performing an aneurysm repair. Choudhury discloses a graft 22 comprising an elongated, foldable material tube 24 mounted in a collapsed formation on upper and lower convoluted expansion rings 32. Slip rings 31 pass through the foldable material tube and around expansion rings 32 to permit the expansion rings to "unwind" while still holding the foldable material tube in place. Elongated, foldable material tube 24 is collapsed around carrier line, catheter tube 34 to facilitate movement of the carrier line tube with graft 22 therearound through a blood vessel. Two expansion lead wires 44 are externally coupled to the two respective expansion rings 32 via carrier line tube 34 and a plurality of slip rings 42. The two expansion lead wires 44 are coupled to the two respective

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expansion rings 32 by slip couplings 46. When graft 22 is properly positioned, the two expansion lead wires 44 are manually pushed against the upper and lower, convoluted expansion rings 32, thereby causing the convolutions to move apart and form a singular ring of larger diameter. As foldable material tube 24 expands, anchoring pins 28 pierce the arterial wall on opposite sides of the aneurysm. The two expansion lead wires 44 are then withdrawn by manually pulling the wires away from the location of the aneurysm to disconnect the wires at slip couplings 46.

In the remarks of this Office action, the Examiner disagreed with applicant's previous arguments regarding the Examiner's use of the Choudhury reference. In support, the Examiner indicated that: "Once the slip rings are removed from the Choudhury device, the spring self expands without balloons, etc. Therefore, self expansion of the Choudhury device is inherent in the design of the stent." The Examiner's attention is directed to column 2, lines 40-44, of the Choudhury reference in which tube 24 is mounted on upper and lower expansion rings 32. Slip rings 31 pass through tube material 24 and around expansion rings 32 to permit the expansion rings to "unwind" while still holding the tube in place. As indicated in column 3, lines 39-44, when graft 22 is properly positioned, expansion lead wires 44 are pushed against the convoluted expansion rings and cause the convolutions of the expansion rings to move apart and form single rings of a larger diameter. Slip rings 31 permit the expansion rings to move relative to the folded expansion tube 24. In FIG. 4 of the reference, slip rings 31 are clearly disclosed as being an integral part of the interconnection of material tube 24 and convoluted expansion rings 32 when in an expanded state.

Applicant submits that slip rings 31 are an integral part of the Choudhury device, and are not removed therefrom. The reference also clearly indicates that convoluted expansion rings 32 are moved apart by expansion lead wires 44 to form single rings of larger diameter. Although expansion rings 32 may have some resiliency, the Choudhury reference clearly indicates that expansion lead wires 44 are manually pushed to cause convoluted expansion rings 32 to move apart. Accordingly, the Choudhury

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reference does not disclose, teach, or even suggest that self expansion of the Choudhury device is inherent in the design of the stent.

As also claimed in independent claims 24 and 27, as amended herein, the transluminal arrangement comprises an introducer sheath having a longitudinal bore therein in which the introducer sheath contains the self expanding spring assembly in a compressed state when the self expanding spring assembly is positioned in the bore of the introducer sheath. This is also not disclosed, taught, or even suggested by the Choudhury reference.

In view of the above, the two convoluted expansion rings 32 of the Choudhury graft are not self expanding spring assemblies contained in a compressed state in the longitudinal bore of an introducer sheath as claimed in claims 24 and 27, as amended herein. Applicant submits that the Choudhury reference does not identically disclose, teach, or even suggest applicant's self expanding spring assembly which is contained in a compressed state in the longitudinal bore of an introducer sheath as claimed in claims 24 and 27, as amended herein, and it is requested that the rejection of these claims under 35 U.S.C. § 102(b) as being anticipated by the Choudhury reference, be withdrawn.

As also previously discussed, the Kreamer reference is directed to aneurysm repair apparatus and method. The Kreamer apparatus includes a triple balloon catheter 50 of which balloons 54, 56, and 58 are externally, sequentially inflated to expand graft 76 next to the wall of a vessel. Like the Choudhury reference, the Kreamer balloons are not self expanding and do not have an introducer sheath having a longitudinal bore therein for containing the balloons or spring assemblies in a compressed state when positioned in the bore of the introducer sheath as claimed in applicant's invention. The Kreamer apparatus includes graft 76 which is covered with a contact adhesive for bonding the graft to the walls of the aorta and iliac arteries. The adhesive coated graft is slid over the triple balloon catheter and secured thereto by spikes which project from the equators of the three balloons. An outer sleeve with little or no affinity for the

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contact adhesive is then placed over the graft to protect the graft from contact with the vessel wall during insertion. The balloon catheter with the graft positioned therearound is inserted into the vessel around the tube of an occlusion catheter, which is positioned in the aorta upstream from the aneurysm. When the graft is properly positioned, the protective outer sleeve is removed, and the balloons are externally, sequentially inflated by the introduction of compressed air via separate inflation tubes 66 in the interior of the balloon catheter. The inflated balloons press the adhesive coated graft against the vessel wall to adhere the graft to the wall. The Kreamer reference does not disclose, teach, or even suggest using the outer sheath to maintain the inflation balloons of the Kreamer apparatus or the expansion rings of the Choudhury reference in a compressed state as claimed in applicant's invention. The Examiner, in her remarks, indicated that the Kreamer reference was used to show a teaching of using a removable sheath for protection of the vessel while introducing the graft. Applicant has now positively recited in independent claims 1, 20, 28, 29, 31, 39, and 40, as amended herein, that the introducer sheath has a longitudinal bore in which the self expanding spring assembly is contained in a compressed state when the self expanding spring assembly is positioned in the bore of the introducer sheath. In the Examiner's remarks, applicant was incorrectly quoted on the bottom of page 11 and the top of page 12. Applicant stated: "Clearly, the Kreamer reference teaches the use of an outer sheath positioned around the graft to prevent the contact adhesive positioned on the outer surface of the graft from prematurely adhering to the surface of the vessel wall during insertion thereof." Although the Examiner was motivated in combining the Choudhury and Kreamer references by this statement, there is no teaching or suggestion in the references to so combine them. Furthermore, there is no motivation for one skilled in the art to combine the references, since the references do not address the problem of containing a self expanding spring assembly in a compressed state when in the

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bore of an introducer sheath, as now positively recited and claimed in applicant's invention.

In view of the above, applicant submits that the Choudhury and Kreamer references, either singly or in combination, do not teach or even suggest a prosthesis having a self expanding spring assembly contained in a compressed state when in the bore of an introducer sheath as claimed in applicant's independent claims 1, 20, 24, 28, 29, 31, 39, and 40, as amended herein, and the claims dependent thereon. Applicant submits that the transluminal arrangement of claims 1, 2, 5, 9-11, 16, 17, 20, 26, and 28-40 is not taught or even suggested by the Choudhury or Kreamer references, either singly or in combination, and it is requested that the rejection of these claims under 35 U.S.C. § 103 as being unpatentable over the Choudhury reference in view of the Kreamer reference, be withdrawn.

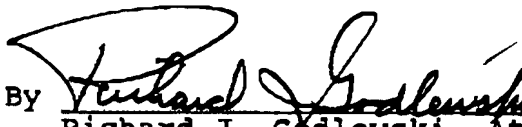
The reexamination and reconsideration of this application is respectfully requested, and it is further requested that the application be passed to issue.

Although the foregoing discussion is believed to be dispositive of the issues in this case, applicant's attorney requests a telephone interview with the Examiner to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment.

Respectfully submitted,

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By


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Date: Nov. 1, 1993

Enclosure:

Petition and Fee for 1-month Extension of Time